Methodist HEALTHCARE

Advancing Skin Health:
The Role of Infra-red Spectroscopy in Comprehensive Assessment Across Diverse Skin Tones

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Background:

- With the development of pressure injuries (PI), structural and chemical changes beneath the skin's surface occurs before any visible signs appear on the outer layers.
- The NPIAP advocates for the implementation of technology to accurately identify tissue at risk for PIs1. Industry leaders highlighted the gaps in knowledge and clinical practice as it pertains to persons of dark skin tones and the presence of PIs.
- Near Infra-red (NIR) spectroscopy is a novel technology that has been used to examine physical and chemical changes in tissues.
- Utilizing an IR spectroscopy scanner (IRSS), researchers in Israel (Maydan et al) completed 1475 scans of patient tissues to include healthy tissue, stage 1 and DTI/sDTI. Results of the study revealed 89% sensitivity and 90% specificity with the scanner's accurate identification of the tissue's status. No safety Signals were identified.

Melanin reduces light penetration in darker skin tones, protecting tissues from UV and visible light, while its lower absorption in the NIR range allows deeper penetration of NIR light, making NIR Spectroscopy useful for clearer visualization of underlying tissues negating pigmentation interference.
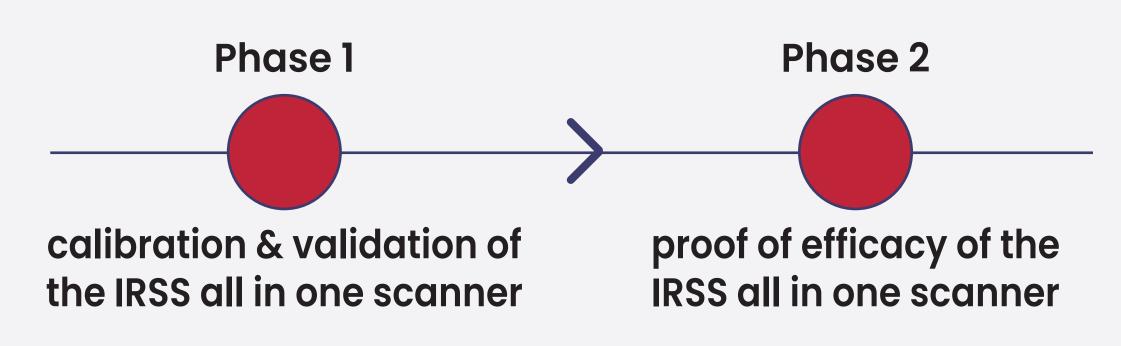
Study Aim

To evaluate IRSS sensitivity and specificity for detecting healthy tissue, Stage 1 and deep tissue (DTI/sDTI) pressure injuries across diverse skin tones as compared to standard nursing skin tissue assessment.

References

Available upon request
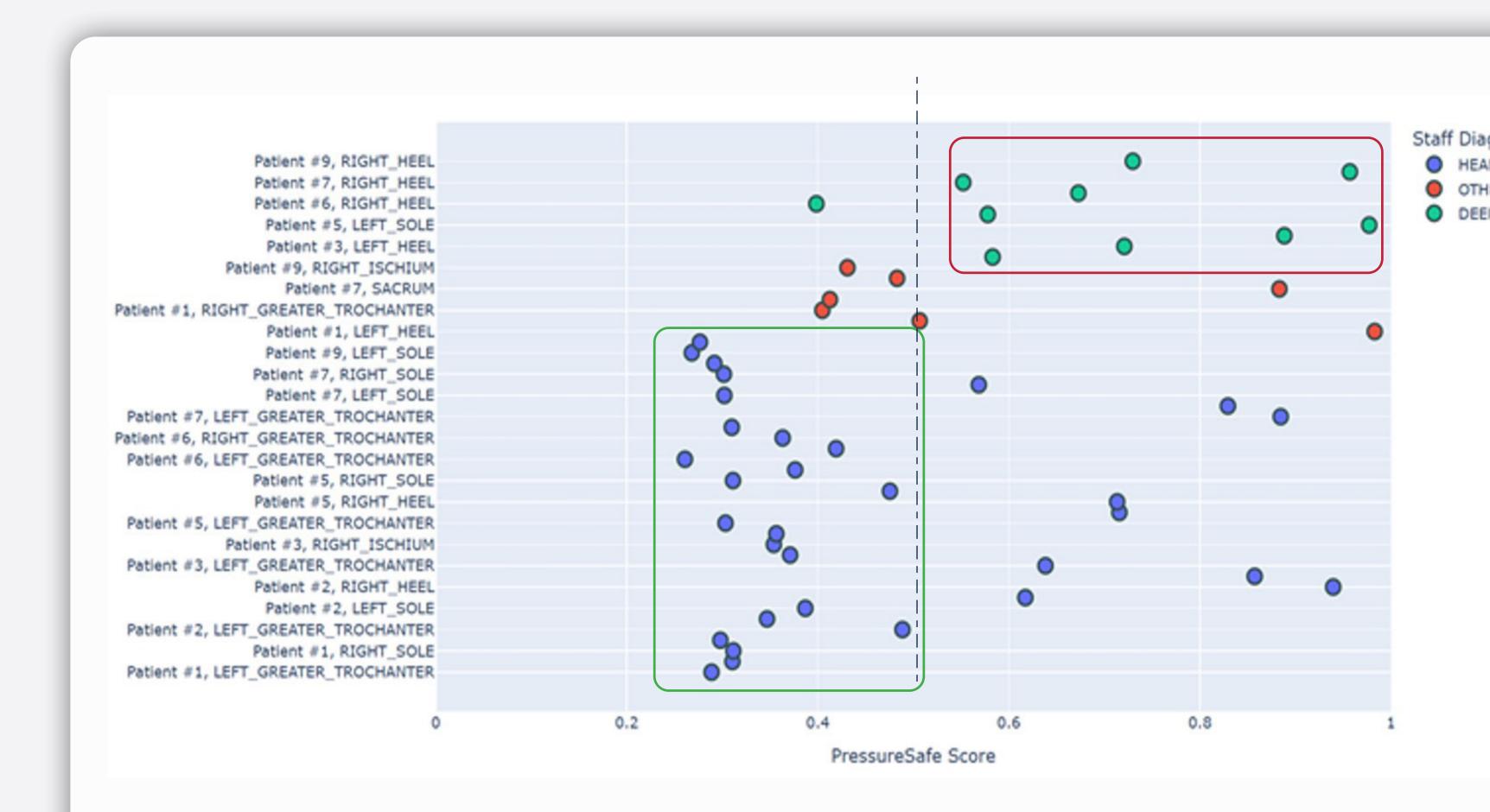
Methodology

- Prospective observational study to investigate performance, safety and usability of IRSS as a diagnostic support tool in an acute-care in two hospitals in the Southcentral, Texas United States.
- Phase 1 (calibration & validation) and WOCN / SN training ongoing; Phase 2 (efficacy) pending.

Phase 1 → Phase 2

calibration & validation of the IRSS all in one scanner

proof of efficacy of the IRSS all in one scanner

- Participants: patients with an identified Stage 1 or DTI/sDTI or identified as at risk for the development of a PI (Braden < 18) with dark skin (Fitzpatrick type 4, 5, or 6).
- IRSS scan of body locations with gentle contact of the scanner head to the areas of interest, each scan completed in < 1 second
- Completed IRSS scan and photograph of 7 anatomical sites (sacrum, bilateral heels, trochanters, and ischium) for each patient to include reference and suspected area.
- Each completed scan automatically uploads to the cloud web-portal which is used for study management. Each WOCN / SN has individual user login for the study.
- A disposable tip was changed between each patient and scanner cleaned per infection control guidelines
- The IRSS technology probes multiple sub-epidermal tissue biomarkers and tissue structural changes.
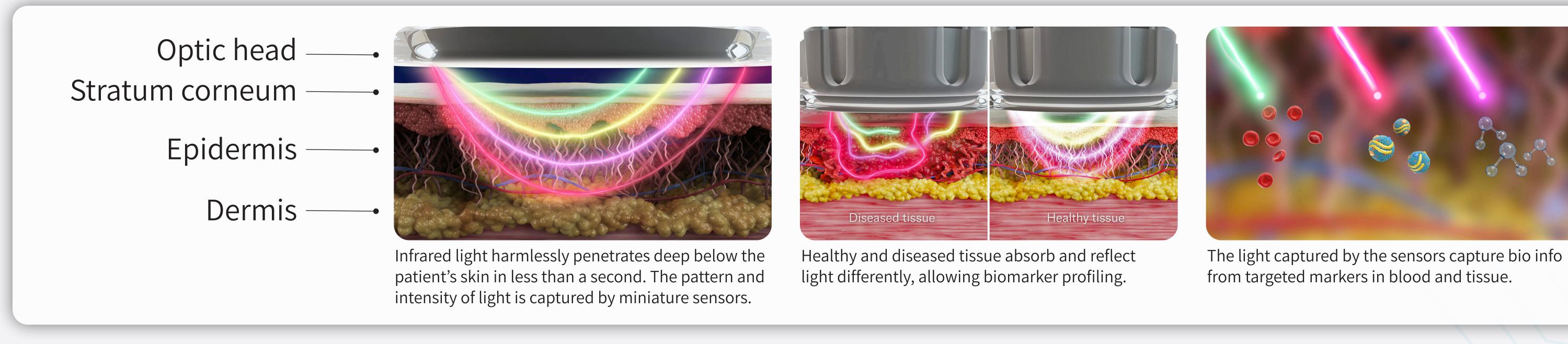- A standard skin assessment documented and used to guide standard of care

Anatomical sites scanning areas

IRSS Technology

- Optic head
- Stratum corneum
- Epidermis
- Dermis

Infrared light harmlessly penetrates deep below the patient's skin in less than a second. The pattern and intensity of light is captured by miniature sensors.

Healthy and diseased tissue absorb and reflect light differently, allowing biomarker profiling.

The light captured by the sensors capture bio info from targeted markers in blood and tissue.

- Handheld non-invasive device scans for biomarker profiles
- LEDs emit and Sensors detect visible light and infrared light patterns
- Bio-information is uploaded to the cloud to AI algorithm that generates a calculated score identifying healthy tissue or probability of "at risk" or "not at risk" for PI

Results

- Phase 1 data: 294 IRSS scans with 49 anatomical sites among a diverse patient population
- Training and validation of the scanner - on going
- 90% sensitivity - on going
- Training of the AI algorithm using data from diverse patient population including dark skin tone with healthy , stage 1 / DTI / sDTI . Including alternative medical conditions to improve algorithm
- No identified safety signals on 294 IRSS scans.

Conclusion

With Phase 1 of the study (calibration and validation) the sensitivity of the IRSS scanner was calculated to be 90% based on a sample of 294 scans across a diverse population. Alternative skin conditions were identified thereby allowing greater AI differential learning by the scanner. The use of the IRSS scanner to assess the underlying tissue with a multi biomarker approach for the detection of a PI, provides a reliable quantitative approach to assist with clinical assessment by health care professionals.

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